# Clinical Policy: Vismodegib (Erivedge)

Reference Number: ERX.SPA.78
Effective Date: 03.01.15
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Vismodegib (Erivedge®) is a Hedgehog pathway inhibitor.

**FDA Approved Indication(s)**
Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma (BCC), or with locally advanced BCC that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Erivedge is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Basal Cell Carcinoma** (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Advanced, recurrent, or metastatic BCC that meets one of the following (i, ii, or iii):
      i. Member has disease that recurred following surgery;
      ii. Member has disease that recurred following radiation;
      iii. Member is not a candidate for surgery or radiation;
   b. Diffuse BCC formation (e.g., Gorlin syndrome or other genetic forms of multiple BCC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Erivedge is prescribed as a single agent;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 150 mg (one capsule) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**
**Commercial –** Length of Benefit
**Medicaid** – 6 months

**B. Medulloblastoma (off-label)** (must meet all)**:**

1. Diagnosis of recurrent medulloblastoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has received prior chemotherapy;
5. Tumor is positive for a sonic hedgehog mutation;
6. Erivedge is prescribed as a single agent;

7. Request meets one of the following (a or b):*
   a. Dose does not exceed 150 mg (one capsule) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**
**Commercial –** Length of Benefit
**Medicaid** – 6 months

**C. Other diagnoses/indications**
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. All Indications in Section I** (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Erivedge for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 150 mg (one capsule) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**
**Commercial** – Length of Benefit
**Medicaid** – 12 months

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*
BCC: basal cell carcinoma
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): none reported
- Boxed warning(s): embryo-fetal toxicity

**V. Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| BCC | 150 mg PO QD | 150 mg/day |

## VI. Product Availability

Capsule: 150 mg

## VII. References

1. Erivedge Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; July 2020. Available at https://www.gene.com/download/pdf/erivedge_prescribing.pdf. Accessed February 14, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 14, 2022.
3. National Comprehensive Cancer Network Guidelines. Basal Cell Skin Cancer Version 1.2022. Available at www.nccn.org. Accessed February 14, 2022.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2018 annual review: Added prescriber requirement. Updated NCCN Compendium supported use in BCC with nodal or distant metastases. Added continuity of care language to section II. Increased approval durations to length of benefit. References reviewed and updated. | 02.08.18 | 05.18 |
| 2Q 2019 annual review: no significant changes; summarized NCCN and FDA approved uses for improved clarity by removing specific requirements for locally advanced, nodal, or distant metastasis (approach aligns with Odomzo); references reviewed and updated. | 02.04.19 | 05.19 |
| 2Q 2020 annual review: NCCN recommended use added for medulloblastoma; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated. | 02.11.20 | 05.20 |
| 2Q 2021 annual review: added BCC criteria for diagnosis of advanced, recurrent or metastatic BCC, previous surgery or radiation therapy if eligible, and use as a single agent for both BCC and medulloblastoma, as these are all supported by the FDA label and/or NCCN; reference reviewed and updated. | 02.02.21 | 05.21 |
| 2Q 2022 annual review: added indication of diffuse basal cell carcinoma (BCC) formation per NCCN category 2A recommendation; references reviewed and updated. | 02.14.22 | 05.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.